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Edwin Southern

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3 RECORD OF ORAL HEARING
4 UNITED STATES PATENT AND TRADEMARK OFFICE

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6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

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10 *Ex parte* EDWIN SOUTHERN
11

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13 Appeal 2009-010829
14 Application 10/772,467
15 Technology Center 1600
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18 Oral Hearing Held: May 13, 2010
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21 Before LORA M. GREEN, FRANCISCO C. PRATS, and
22 JEFFREY N. FREDMAN, Administrative Patent Judges.
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24
25 ON BEHALF OF THE APPELLANT:
26

27
28 WARREN M. CHEEK, ESQ.
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1 The above-entitled matter came on for hearing on Thursday,
2 May 13, 2010, commencing at 9:59 a.m., at the U.S. Board of Patent
3 Appeals and Interferences, Madison Building, East Wing, 600 Dulany
4 Street, 9th Floor, Alexandria, Virginia, before Jon Hundley, Notary Public.

5 THE USHER: Calendar No. 58, Appeal Number 2009-010829.
6 Mr. Cheek.

7 JUDGE GREEN: Thank you. Good morning, Mr. Cheek.

8 MR. CHEEK: Good morning.

9 JUDGE GREEN: If you have a card for the transcriptionist,
10 that would be greatly appreciated.

11 MR. CHEEK: I do.

12 JUDGE GREEN: We are familiar with the facts of your case.
13 You have 20 minutes whenever you would like to begin.

14 MR. CHEEK: Thank you very much. Good morning. My
15 name is Warren Cheek. I'm with the firm of Wenderoth, Lind & Ponack,
16 and I'm here representing the Appellant, Edwin Southern, in this Appeal,
17 Serial No. 10/772,467.

18 As a preliminary matter, I'd just like to mention that in the
19 Appellant's Brief, it's noted there are two related Patents of the inventor,
20 USP 5,700,637 and USP 6,054,270. Both of these Patents are mentioned in
21 the brief as being involved in a re-examination proceeding at the time of
22 filing the Brief.

23 Since that time, the re-examination proceedings have been
24 concluded, and in both Patents, re-examination certificates have issued with
25 numerous claims. There were some amendments to the claims.

1 Turning to this Appeal, there is a single ground of rejection of
2 the Claims under 35 U.S.C. 103. The Claims on appeal and under rejection
3 are Claims 17-26 and 86-87. These Claims are rejected as unpatentable over
4 the teachings of Stavrianopoulos, USP 4,994,373, and Matkovich, USP
5 4,828,386.

6 Before getting into the details of the rejection, I'd like to
7 mention there are four groupings of claims that are separately argued in the
8 Brief, so the Appellant would respectfully request the Board's consideration
9 of each grouping of claims with respect to the rejection.

10 Briefly, for your convenience, I'll summarize the groupings.
11 Group one is Claims 17-22 and 26-27. Claim 17 is the main independent
12 claim, the broadest claim, and is directed to an apparatus for analyzing the
13 polynucleotide using oligonucleotides attached to a support. The details of
14 Claim 17 will be addressed in just a minute.

15 Claims 18-22 and 26-27 are dependent upon Claim 17 and are
16 not separately argued.

17 Group two is Claims 23 and 86. Claim 23 is dependent upon
18 Claim 17 and requires that the oligonucleotides, which are attached to the
19 support, are covalently attached. Claim 86 is an independent claim and is
20 essentially the combination of Claims 17 and 23.

21 Group three is Claims 24 and 87. Claim 24 depends on Claim
22 17 and requires that the oligonucleotides be attached to the support by a
23 terminal oligonucleotide. Claim 87 is dependent upon 86 and recites the
24 same limitation.

1 Lastly, group four is Claim 25. This is dependent upon Claim
2 17 and requires the oligonucleotide to be synthesized in situ.

3 Turning now to the main independent Claim 17, I'd just like to
4 briefly summarize its features. It's a short claim. Apparatus for analyzing a
5 polynucleotide. The first requirement being the apparatus comprise a
6 support having an impermeable surface with porous material attached to the
7 impermeable surface.

8 The second requirement for simplicity I will describe as the
9 next recited feature of Claim 17, an array of oligonucleotides with
10 predetermined sequences attached to the porous material.

11 The third requirement follows the second requirement of the
12 claim. The array must comprise at least two defined cells and the sequence
13 of the oligonucleotides in a first cell is different from the sequence of
14 oligonucleotides in a second cell.

15 Lastly, in the claim as it's recited, the fourth requirement being
16 the oligonucleotides are shorter than the polynucleotide to be analyzed.

17 Any questions up to this point? This is pretty basic.

18 JUDGE GREEN: We understand all that.

19 MR. CHEEK: Thank you. Turning to the rejection, it is first
20 respectfully submitted that the rejection is improper as being based upon
21 non-analogous art. The present invention is directed to an apparatus for
22 analyzing a polynucleotide, similarly, the primary reference to
23 Stavrianopoulos is also directed to an apparatus for analyzing a
24 polynucleotide.

1 However, the secondary reference relied upon by the Examiner,
2 Matkovich, is directed to an entirely different apparatus, which is directed to
3 increasing the reliability and sensitivity of an antibody microtiter well.

4 The concept of the secondary reference as explained in the
5 reference is to try to improve the reliability and sensitivity of an antibody
6 microtiter well. The invention --

7 JUDGE FREDMAN: Basically what the Examiner is saying is
8 these are analogous because these are both assays which are using coupling
9 and basically Matkovich simply shows that covalent coupling is a way you
10 can attach the agent to the array. I think that is something we want to focus
11 on.

12 My question on predetermined, which I think is the central
13 question, to me, when you say "predetermined," I think of that as a product
14 by process limitation. In other words, it doesn't structurally impact the array
15 itself; right?

16 If there are two different arrays, I take an array and I
17 predetermine what I put on it and I have molecules A, B and C, and you
18 have an array and you put on A, B and C, but you didn't decide what they
19 were in advance, that's just what's on your array, we end up with arrays that
20 are potentially identical arrays, simply the difference being I decided what to
21 put on them first and you didn't. Can you explain why that isn't the case?

22 MR. CHEEK: That isn't the case, and it is respectfully
23 submitted it's not a product by process limitation because the meaning of the
24 term "predetermined," which originates from Examiner Artin Marschel, who
25 originally allowed it, and at that time, we were contemplating the term

1 "known," and there is a long history, but it was agreed that "predetermined"
2 was a very accurate way of describing that each and every oligonucleotide,
3 the sequence of each and every oligonucleotide on the array is known, and
4 that's not a product by process limitation. You could make it into one.

5 JUDGE FREDMAN: How does that change the array?

6 MR. CHEEK: The array -- the main difference between our
7 apparatus and Stavrianopoulos' is in Stavrianopoulos, the sequences are
8 unknown that are immobilized and the known sequences -- we have totally
9 known sequences.

10 JUDGE FREDMAN: I understand the differences. It's not a
11 question of understanding the invention. It's a question of from a structural
12 standpoint, how does the structure differ based on what the Inventor knows?

13 MR. CHEEK: The structure differs because there are -- in most
14 of the embodiments, there are thousands of cells of different
15 oligonucleotides.

16 JUDGE GREEN: That is not what you're claiming. Claim 17
17 only has two different -- that's what we have to focus on. If you have two
18 oligo's immobilized and in one case, like Judge Fredman says, one person
19 knows the structure or the sequence of the oligo's and in the second case, the
20 person using it does not, how does the structure itself differ in those two
21 particular cases, just because one person knows the sequence and the second
22 person doesn't?

23 Suppose someone was using the array, the second person picks
24 it up but doesn't know what the sequences are, does that mean it no longer
25 falls within your claim?

1 MR. CHEEK: Yes.

2 JUDGE GREEN: The same piece of equipment. The first
3 person knows what the sequences are, the second person doesn't because
4 they are just picking it up and putting it away, that person would not be
5 infringing because he doesn't know what the sequences are.

6 JUDGE FREDMAN: In a product claim.

7 JUDGE GREEN: In a product claim.

8 MR. CHEEK: I could also say that's not part of the rejection.

9 JUDGE GREEN: No, but we're just trying to figure out the
10 scope of your claim.

11 MR. CHEEK: The scope of the claim is that the apparatus has
12 a support and the entire sequence of every oligonucleotide is known on the
13 support such that when something binds to that oligonucleotide, you can
14 look it up and know exactly what the sequence is of the probe that binds to
15 it.

16 JUDGE GREEN: That relates more to a method of using than
17 to the apparatus itself.

18 MR. CHEEK: We would respectfully disagree. This is a
19 central issue but it's not the only issue as to why the rejection should be
20 overturned.

21 The fourth limitation of the claim is that the oligonucleotides
22 are shorter than the polynucleotide. There is absolutely no mention in the
23 Rejection or in the Examiner's Answer as to why the prior art teaches or
24 suggests that feature.

1 JUDGE FREDMAN: Again, that is really a process limitation
2 because the polynucleotides coming in are entirely dependent on what the
3 experimenter chooses. That doesn't change the array. It depends on what is
4 being done to the array. You're trying to import a limitation of a method of
5 use in which the polynucleotides being used are longer. That is really not a
6 product limitation; right?

7 I think there are ways this could be written, although I'm not
8 entirely sure or I would suggest them, to incorporate these as structural, but I
9 don't know that this claim captures that.

10 I would actually ask if we could jump for one second, you may
11 want to say more about 17, but I'd like to go to 25 for a second.

12 MR. CHEEK: Yes, sir.

13 JUDGE FREDMAN: 25 says in situ. Again, that is a method
14 of limitation, but in the context here for 25, it seems to me the implication of
15 in situ is essentially it doesn't depend on 24, it depends on 17, but I'm
16 unaware at the time of filing any way of doing in situ synthesis other than by
17 a terminal oligonucleotide covalent attached to the support.

18 I think that is what your spec shows. Is there any other way?
19 In other words, when you say "in situ synthesis," can that mean something
20 other than covalent attached by a terminal oligonucleotide or is that really
21 required?

22 MR. CHEEK: I'm not sure. I could contact the inventor. I'm
23 sorry, I don't know.

24 JUDGE GREEN: There is nothing in your specification that
25 would imply it means anything differently?

1 MR. CHEEK: No, not to my knowledge.

2 JUDGE FREDMAN: In light of your spec, we could read it as
3 requiring the covalent attachment potentially.

4 MR. CHEEK: Potentially.

5 JUDGE FREDMAN: That is a reasonable way of reading it.

6 MR. CHEEK: Yes, I'd have to agree with that, at least as a
7 potential interpretation.

8 JUDGE FREDMAN: Right.

9 MR. CHEEK: Another point that I'd like to address is the third
10 requirement of the claim that the array comprises at least two defined cells,
11 the sequence of the oligonucleotides in the first cell is different from the
12 sequence of the oligonucleotides of the second cell.

13 The Examiner has two arguments for this, neither of which it is
14 respectfully submitted are reasonable. One argument is that the primary
15 reference, Stavrianopoulos, teaches in the examples of making constructs
16 with different DAS, such as lambda or adenovirus. However, these
17 constructs are taught in different examples.

18 There is absolutely no suggestion in the reference to combined
19 different DNA samples into a single construct, and even if you did,
20 according to this hypothetical, the Stavrianopoulos assay wouldn't work
21 because you then have two analytes of unknown sequences on the support
22 and you wouldn't know what it was binding to.

23 It simply wouldn't work. On this single basis alone, the
24 rejection is untenable.

1 JUDGE PRATS: I'm looking at Column 8, I think that is the
2 portion the Examiner cited, Column 8, line 41. "For example, glass plates
3 provided with an array of depressions or wells would have samples of the
4 various analytes deposited therein, the single stranded analytes being fixed
5 to the surfaces of the wells."

6 Doesn't that kind of suggest you could have different samples
7 on each of the wells? I think that's what the Examiner is trying to say. I
8 understand your point about the different examples. He picks lambda and
9 adenovirus from one of the other examples.

10 It seems that passage right there at Column 8 --

11 MR. CHEEK: The Examiner has latched onto that one word,
12 "various," and it's our position that the Examiner's interpretation of the
13 sentence and that term "various" is unreasonable. Only in pure hindsight, if
14 you read the entire specification of Stavrianopoulos, it solely talks about a
15 single analyte on the surface, and I would just mention that as you can
16 appreciate it, if you have two unknown analytes on a surface, you don't
17 know which the known sequence probe that is in solution phase is going to
18 bind to.

19 What is a more reasonable explanation --

20 JUDGE FREDMAN: Stavrianopoulos teaches you can use
21 multiple or different labels. You could just label two different things
22 with -- two different probes with two different labels.

23 MR. CHEEK: He doesn't teach putting two -- this is the only
24 word in the specification that you could construe as the Examiner has to
25 mean different sequences on the surface.

1 It's my suggestion that the real meaning of this and still, it's not
2 entirely known for sure, but the sentence begins "Glass plates provided with
3 an array of depressions or wells which would have samples of various
4 analytes."

5 My interpretation is that there are different plates with different
6 samples. Nevertheless, there is only the same sample on each plate. I think
7 that is a more reasonable interpretation of that sentence.

8 To rely upon that single word "various" in the entire
9 specification to mean something totally different than what the remainder of
10 the specification does, it just seems to be unreasonable to us.

11 JUDGE FREDMAN: We also talk about how one ordinary in
12 the skill would be able to understand these things. The skill level at the time
13 of invention, do we analyze one thing at one time or do we analyze multiple
14 things.

15 MR. CHEEK: At the time of this invention, back in 1988, this
16 was cutting edge. There was no such --

17 JUDGE FREDMAN: When is your filing date?

18 MR. CHEEK: It relies upon a British application in 1988.

19 JUDGE FREDMAN: I've actually looked at these before in my
20 career.

21 Even in 1988 and before that, there were arrays, there were
22 things, for example --

23 MR. CHEEK: But not on such a support as this.

24 JUDGE FREDMAN: I think you even had them on glass. The
25 real difference here is these are really microarrays, you don't quite capture

1 that because you don't put in the limitation of dots per inch, which often will
2 distinguish these.

3 MR. CHEEK: That is deep in the claim.

4 JUDGE FREDMAN: That's the real difference here. It's not
5 captured by the claim, by the independent claim.

6 MR. CHEEK: I know there are just a few minutes left. I just
7 would like to briefly touch on the other groups of claims, which I'm not sure
8 we talked about, Claims 23 and 86 requires an oligonucleotide to be attached
9 covalently. Stavrianopoulos clearly teaches only non-covalent ionic
10 attachment. I think we have established that in the record.

11 The secondary reference mentions covalent attachment but
12 that's only in a generic type of way, and due to the non-analogous nature of
13 the secondary reference, it's our suggestion that one skilled in the art would
14 not have been motivated to modify the non-covalent ionic attachment of the
15 primary reference with this type of covalent attachment.

16 On this issue of non-analogous art also, the Examiner has
17 broadly defined this as a field of attachment of macromolecules, but it's our
18 submission that the field that one skilled in the art making polynucleotide
19 arrays would not really look to this.

20 The field in our position is much narrower than that, and why
21 would one skilled in the art look to a reference in the antibody microtiter
22 well art, which is trying to improve sensitivity of microtiter wells, in
23 designing a polynucleotide array for detecting single based differences in
24 analyte nucleotides.

1 JUDGE PRATS: If I may, doesn't the Examiner actually also
2 point to Column 6, I understand the focus of Matkovich, it actually seems to
3 be antibodies, but there is this blurb in Column 6, line 60, saying you can
4 also use it for a bunch of other things including -- the last item is nucleic
5 acids.

6 Does that get the Examiner outside of the analogous argument?

7 MR. CHEEK: We don't think so. Just because it's a blurb that
8 mentions, as you say, and we agree, it's a blurb that mentions a word. It
9 doesn't really change the interest of one skilled in the art in terms of trying to
10 make a polynucleotide array. The art is different and probably one skilled in
11 the art wouldn't be looking at this antibody microtiter well to see any vague
12 general teachings such as that.

13 Lastly, Claims 24 and 87, these require attachment of the
14 oligonucleotides by a terminal oligonucleotide. The Examiner simply says
15 well, this is encompassed by attachment taught by the references.

16 JUDGE FREDMAN: There is no specific teaching of that;
17 right?

18 MR. CHEEK: No, definitely not. In fact, the Examiner agrees
19 on that. It's in the Answer. She says it's encompassed. We would submit
20 that being encompassed is not the same thing as being a teaching or
21 suggestion, which would motivate somebody to make something according
22 to our claim.

23 From the standpoint of what the art was at the time, the art of
24 attaching nucleic acids to porous supports at the time involved usually
25 internal adenovirus type attachments.

1 At the time of the invention, it really was not something that
2 would be automatically envisioned, much less the references don't enable
3 one to prepare this embodiment.

4 It is respectfully submitted that at least Claims 24 and 87 are
5 clearly not obvious over the cited references and for all the other reasons, the
6 remainder of the claims as well.

7 JUDGE GREEN: I think we understand your argument. Do
8 you have any further questions?

9 (No response.)

10 JUDGE GREEN: Thank you.

11 MR. CHEEK: We sincerely appreciate your consideration;
12 good questions.

13 JUDGE FREDMAN: Thank you.

14 Whereupon, at 10:22 a.m., the proceedings were concluded.

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